



*Small Business Innovation Research (SBIR)  
Small Business Technology Transfer (STTR)*



# Overview of the HHS SBIR/STTR Programs: Research & Educational Opportunities at NIH

NASA HBCU/MSI Technology Infusion Road Tour  
University of Nevada - Las Vegas

January 10 - 12, 2017

**Robert Vinson**

SBIR/STTR Program Manager; Office of Extramural Research, NIH





Small Business Innovation Research (SBIR)  
Small Business Technology Transfer (STTR)

# SBIR/STTR Website



The header features a background image of laboratory equipment. On the left is the NIH SBIR/STTR logo. A blue navigation menu on the left lists: SBIR/STTR HOME, ABOUT, FUNDING, APPLY, REVIEW, POLICY, TECHNICAL ASSISTANCE, RESOURCES, STATISTICS AND SUCCESSES, and ENGAGE AND CONNECT. Below this menu is a yellow button labeled 'New to SBIR/STTR'. On the right, there is a search bar with 'A- | A+ | Q' and the SBIR/STTR logo with the tagline 'America's Seed Fund'. A white box on the right contains the text 'NIH Technical Assistance Programs' and 'CELEBRATING OVER 11 YEARS'. Below this are two dark blue buttons: 'Niche Assessment Program (NAP)' and 'Commercialization Accelerator Program (CAP)'. At the bottom of the header is a row of icons and labels: Technical Assistance Programs, Funding, Electronic Submission Process, Success Stories, Contact Us, and Engage and Connect.

## What are SBIR and STTR Programs?


The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.


In Fiscal Year 2016, NIH's SBIR and STTR programs will invest over 870 million dollars into health and life science companies that are creating innovative technologies that align with NIH's mission to improve health and save lives. A key objective is to translate promising technologies to the private sector and enable life-saving innovations to reach consumer markets.


We invite you to explore our website to learn more about **NIH's SBIR & STTR** programs, or get started on an application!

### HHS SBIR/STTR COMPONENT PROGRAM LINKS

#### NEWS

 Q&A Amendment for the HHS SBIR Contract PHS 2017-1 Now Available **NEW**  
September 22, 2016

 I-Corps at NIH – Learn more during the Informational Webinar on Sept 28  
September 21, 2016

 Early Bird Registration Deadline has been Extended – Register Now and Save!  
September 1, 2016

<http://sbir.nih.gov>





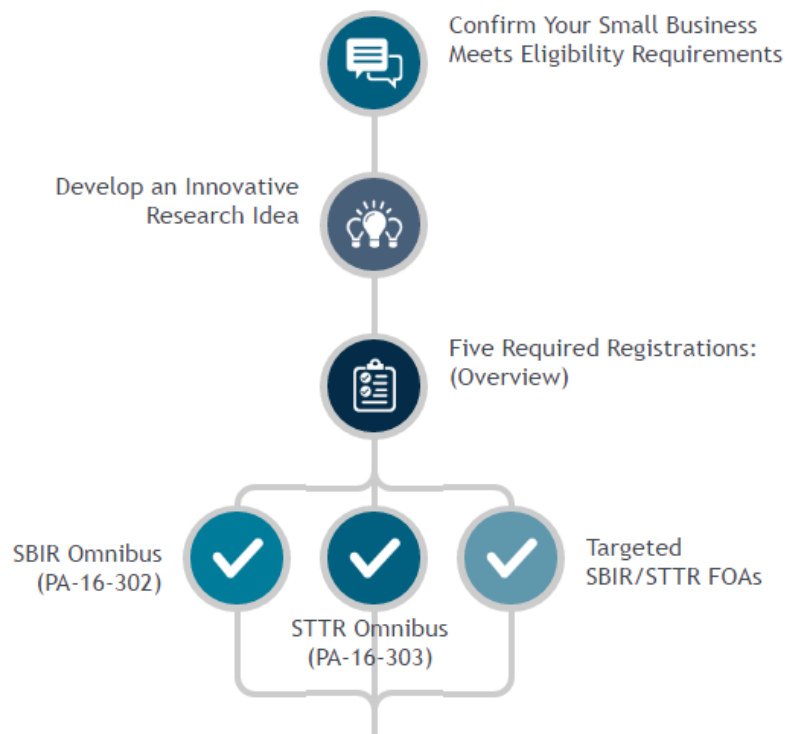
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# New to SBIR/STTR?

## SBIR/STTR Application Process Infographic

Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click through the chart for answers to your related questions.

**START THE SBIR/STTR  
APPLICATION PROCESS  
INFOGRAPHIC**



<http://sbir.nih.gov/infographic>





3.2%

## **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

Set-aside program for small business concerns to engage in federal R&D - with potential for commercialization

0.45%

## **SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions - with potential for commercialization





- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

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*Small Business Innovation Development Act of 1982*

P.L. 112-81 Re-Authorizes program through FY2017





- Stimulate and foster scientific and technological innovation through **cooperative research** and development carried out **between small business concerns** and **research institutions**
- Foster **technology transfer** between small business concerns and research institutions

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## *Small Business Research and Development Enhancement Act of 1992*

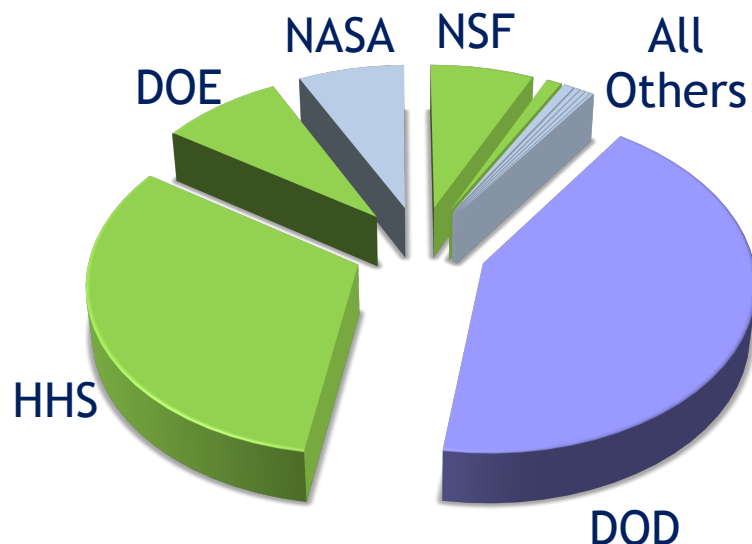
P.L. 112-81 Re-Authorizes program through FY2017





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# SBIR/STTR Agency Budgets



Agencies with SBIR and STTR Programs	Budget
Department of Defense (DOD)	\$1.070B
Department of Health and Human Services (HHS), including the National Institutes of Health (NIH)*	\$797M
Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)	\$206M
National Aeronautics and Space Administration (NASA)	\$180M
National Science Foundation (NSF)	\$176M
Agencies with SBIR Programs	Budget
U.S. Department of Agriculture (USDA)	\$25.3M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$17.7M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*	\$8.4M
Department of Transportation (DOT)	\$7.9M
Department of Education (ED)	\$7.5M
Environmental Protection Agency (EPA)	\$4.2M





Small Business Innovation Research (SBIR)  
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## HHS Program Funding

2016 Budget	SBIR	STTR
NIH	\$763M	\$114M
CDC	\$9.0M	N/A
ACL (NIDILRR)	\$2.7M	N/A
FDA	\$1.6M	N/A
ACF	\$94K	N/A







Small Business Innovation Research (SBIR)  
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# Three-Phase Program



*Discovery*

Phase I

## Phase I Feasibility Study

**Budget Guide:** \$150K for SBIR and STTR

**Project Period:** 6 months (SBIR); 1 year (STTR)



*Development*

Phase II

## Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase IIB

## Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA  
Many, but not all, IC's participate  
Varies~\$1M per year; up to 3 years



*Commercial*

Phase III

## Phase III Commercialization Stage

NIH, generally, not the “customer”

Consider partnering and exit strategy early



# SBIR Eligibility Criteria

- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the US (with few exceptions)
- Individual Ownership:
  - Greater than 50% US-owned by individuals and independently operated OR
  - Greater than 50% owned and controlled by other business concern/s that is/are greater than 50% owned and controlled by one or more individuals OR
  - Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (For FOAs after 1/28/2013 NIH; 7/10/14 CDC)

**Determined at Time of Award**





# STTR Eligibility Criteria

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- US Research Institution
  - College or university; other non-profit research organization; Federal R&D center
- Intellectual Property Agreement
  - Allocation of rights in IP and rights to carry out follow-on R&D and commercialization



- Eligibility is determined at **time of award**
- PD/PI is not required to have a Ph.D./M.D.
- PD/PI is required to have expertise to oversee project scientifically and technically
- Applications **may be** submitted to **different agencies** for similar work
- Awards may not be accepted from different agencies for duplicative projects



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# Mission



***To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***

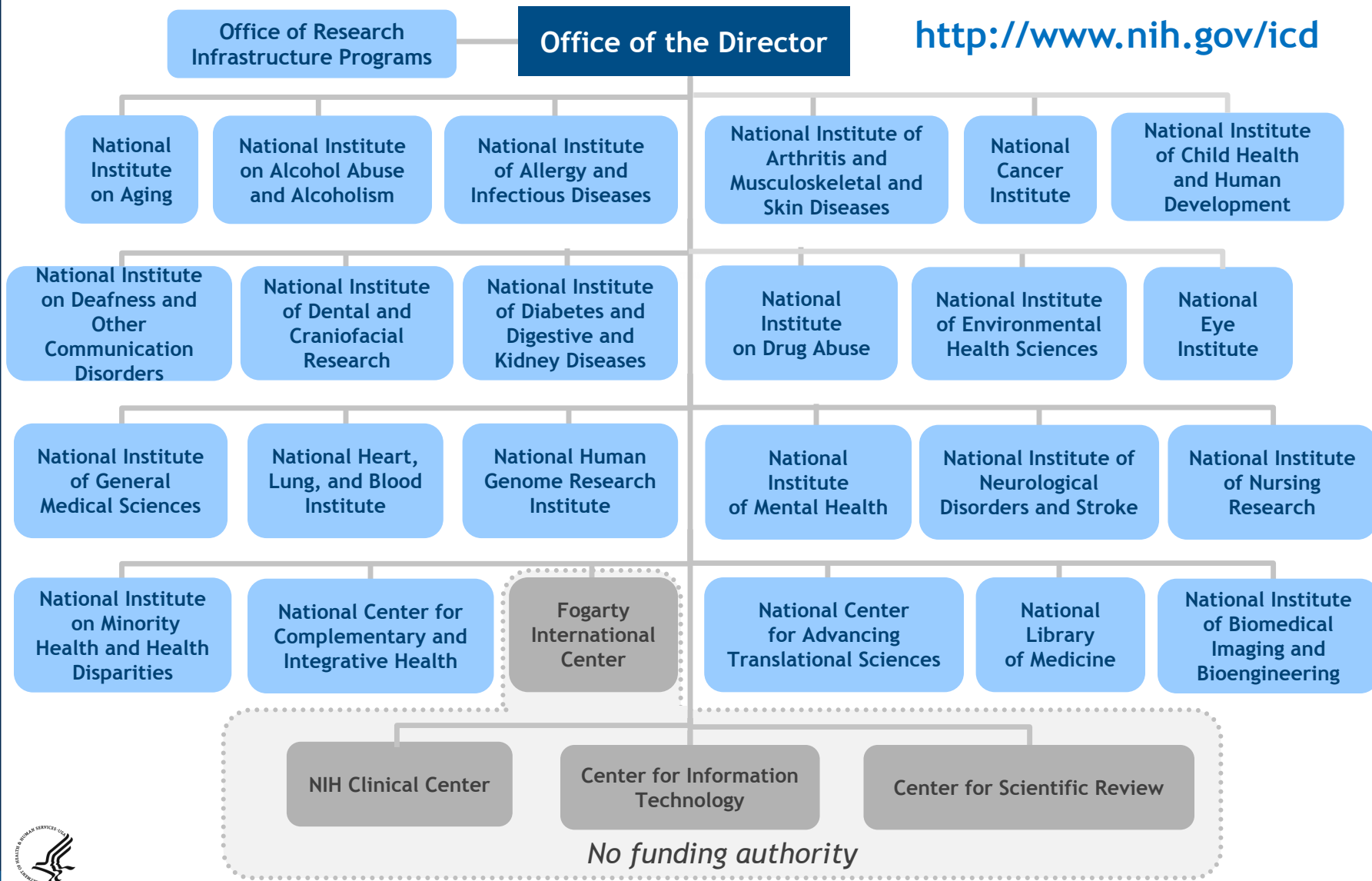




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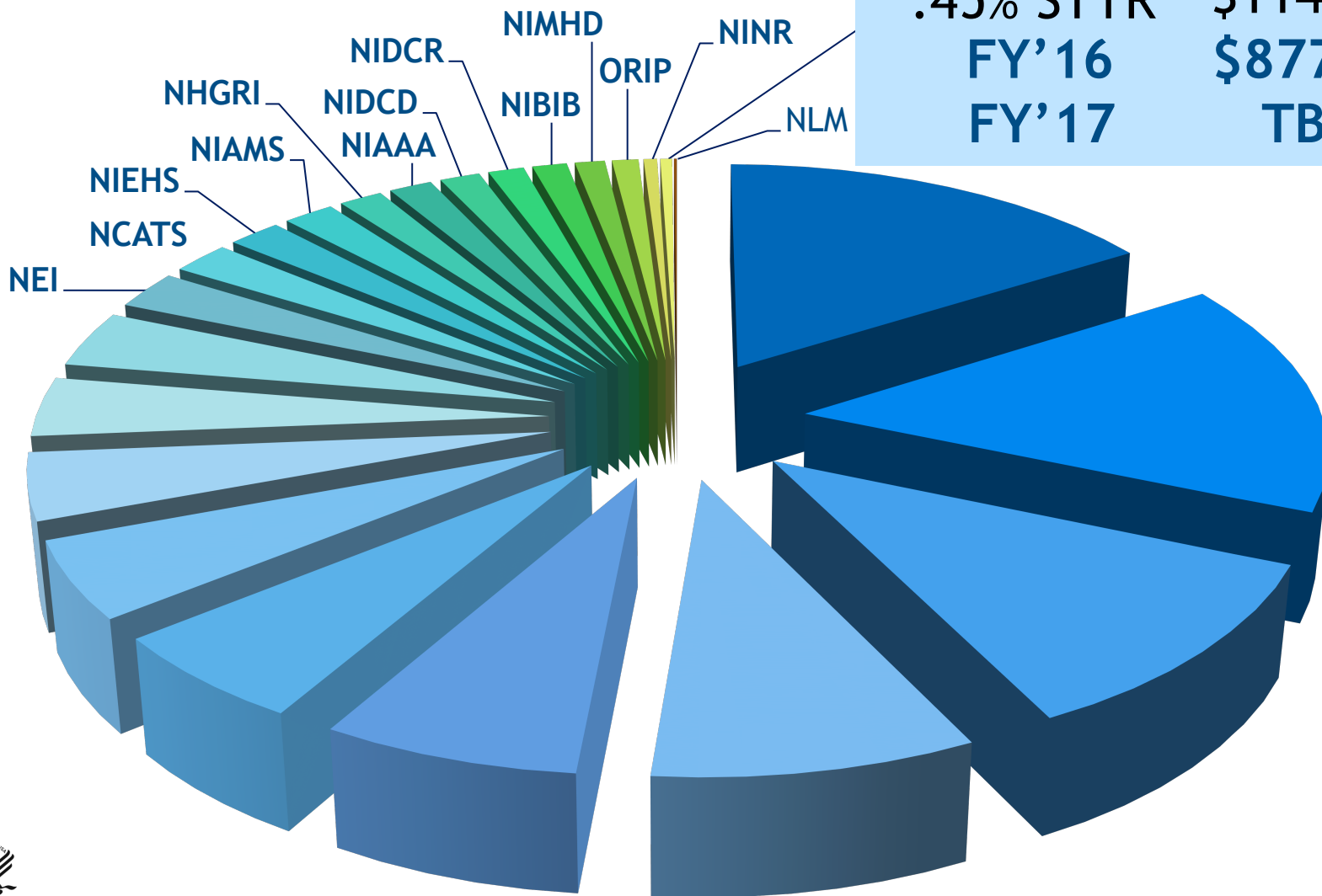
# National Institutes of Health

<http://www.nih.gov/icd>



# SBIR/STTR Budget Allocations FY'16

3.00% SBIR	\$763M
.45% STTR	\$114M
<b>FY'16</b>	<b>\$877M</b>
<b>FY'17</b>	<b>TBD</b>





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# NIH-wide SBIR/STTR Grant Success Rates 2015

Fiscal Year	SBIR/STTR	Phase	Number Applications Reviewed	Number Applications Awarded	Success Rate	Total Funding
2015	SBIR	Fast Track	337	66	19.6%	\$18,157,545
2015	SBIR	Phase I	3,425	514	15.0%	\$117,110,555
2015	SBIR	Total Phase II	823	241	29.3%	\$179,946,727
		Regular Phase II				
2015	SBIR	II	442	163	36.9%	\$113,088,150
2015	SBIR	Direct Phase II	347	65	18.7%	\$55,150,363
2015	SBIR	Phase IIB	34	13	38.2%	\$11,708,214
2015	STTR	Fast Track	61	10	16.4%	\$2,171,909
2015	STTR	Phase I	911	149	16.4%	\$33,782,224
2015	STTR	Total Phase II	87	31	35.6%	\$21,597,183
		Regular Phase II				
2015	STTR	II	87	31	35.6%	\$21,597,183
2015	FY TOTAL		5,644	1,011	17.9%	\$372,766,143

Success Rates Posted Online: [http://report.nih.gov/success\\_rates/index.aspx](http://report.nih.gov/success_rates/index.aspx)







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# SBIR/STTR FOAs

The screenshot shows the NIH SBIR/STTR website. At the top, the NIH logo is on the left, and the text "Small Business Innovation Research (SBIR) Small Business Technology Transfer (STTR)" is in the center. On the right, there is a search bar with "A- A+ SEARCH" and a magnifying glass icon. Below the header, there is a navigation menu on the left with links: SBIR/STTR HOME, ABOUT, FUNDING, APPLY, REVIEW, POLICY, TECHNICAL ASSISTANCE, RESOURCES, STATISTICS AND SUCCESS, and ENGAGE AND CONNECT. A yellow button labeled "New to SBIR/STTR" is also present. The main content area features a large image of a hand holding a pen over a document titled "Planning Research". Below this, the text reads: "STTR Omnibus grant solicitation for small businesses, which allow small businesses to submit priority research areas for the US Department of Health and Human Service (HHS) SBIR and STTR programs at each of the 24 participating NIH Institutes and Centers (ICs), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) and the Administration for Children and Families (ACF). You may perform a 'Ctrl-F' keyword search to identify NIH ICs that have overlapping program priorities with your research topic, and also use NIH Matchmaker to conduct keyword searches of your topic to identify ICs that have funded research in your area. With any specific idea, you should speak directly with the program official to gauge their interest. Click here to view the Fiscal Year 2015 SBA approved topics for budget waivers." Below this, there is a section titled "Funding Opportunities for U.S. Small Businesses" which states: "If your small business concern (SBC) decides to apply, please use the SF424 (R&R) SBIR/STTR Application Guide (Version C), and the Annotated SF424 (R&R) SBIR/STTR Form Set (FORMS-C) for step-by-step instructions on how to complete the application. Both grant and contract applications require separate forms or appendixes to be attached. Whether an attachment is required or not is often based on how you answer specific questions throughout the application (ie: related to human subject's research). You may find these forms or appendixes in your grant application package that you download from Grants.gov, or you may also access them online, here."

<https://sbir.nih.gov/funding>





- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation  
“Parent” FOAs: [SBIR: PA-16-302](#) [STTR: PA-16-303](#)

Release: June 3, 2016

Standard Due Dates: September 5<sup>th</sup>, January 5<sup>th</sup>, **April 5<sup>th</sup>**

- SBIR Contract Solicitation (NIH, CDC)  
Program Solicitation [PHS 2017-1](#) (SBIRs Only)  
NIH Guide Notice [NOT-OD-16-123](#)  
Released: Aug. 1, 2016    Closed: Oct. 21, 2016 (5pm EDT)
- [NIH Guide for Grants and Contracts](#)  
Release: Weekly receipt dates specified in each FOA





	Omnibus	Targeted
Due Dates	Standard Due Dates	Standard or Customized Due Dates
Review	SBIR/STTR panels at CSR	SBIR/STTR panels at CSR <b>OR</b> SBIR/STTR panel at IC
Application Instructions	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set <b>AND</b> any additional instructions in FOA

**Read FOA very carefully!**





SBIR/STTR grant applications and SBIR contract proposals must be submitted electronically.

## Registrations are required!!!

- DUNS Number (Company)
  - System for Award Management (SAM)
  - Grants.gov (Company)
  - eRA Commons (Company and all PD/PIs)
  - SBA Company Registry at SBIR.gov
- Helpful [NIH Grants Registration Infographic](#)
  - For contracts, submit proposals with [electronic Contract Proposal Submission](#) (eCPS) website





# WOSB and SDB Definitions

## What is a Women-Owned Small Business (WOSB)?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women (who must be US citizens)
- The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry
- SBCs self certify on the SF 424 (R&R) Form

## What is a Socially and Economically Disadvantaged Business (SDB)?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged
- The firm must be small, according to SBA’s [size standards](#)
- You must self-certify by registering your business in the [System for Award Management](#)





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# Application & Review Process



Applicant initiates research idea



Small Business Concern confirms Eligibility



Submits SBIR/STTR grant application to NIH electronically



NIH Center for Scientific Review assigns to IC and IRG

1-2 Months



IC staff prepare funding plan for IC Director



Advisory Council or Board recommend Approval

3 Months



Scientific Review Group evaluates scientific merit

2-4 Months



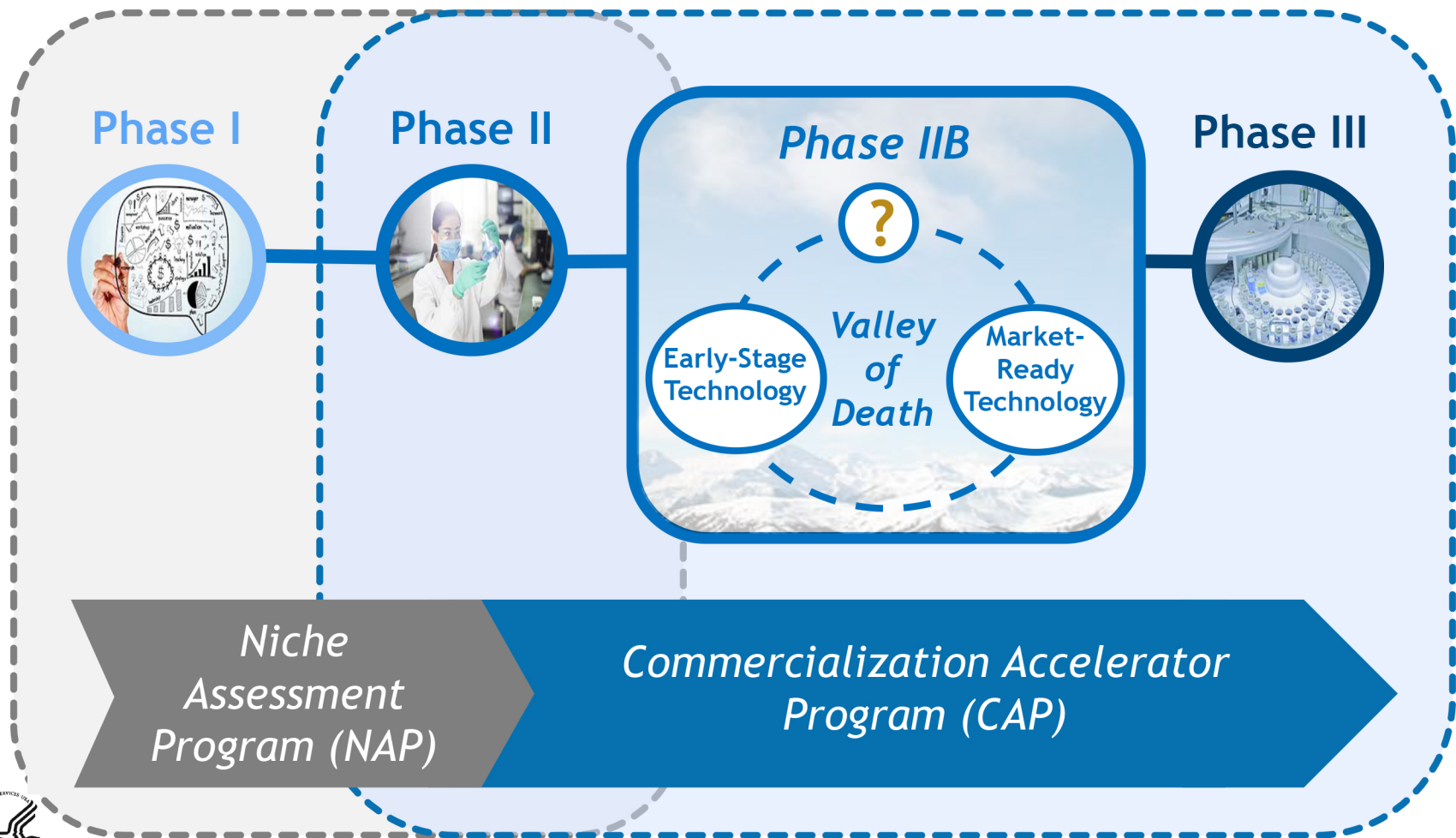
IC allocates funds



Grantee conducts research



## Helping companies cross the “Valley of Death”





### Niche Assessment Program Foresight S&T

(Phase I awardees)

- Identifies other uses of technology
- Determines competitive advantages
- Develops market entry strategy



### Commercialization Accelerator Program Larta, Inc.

(Phase II awardees)

- “Menu” of technical assistance/training programs in:
  - Strategic/business planning
  - FDA requirements
  - Technology valuation
  - Manufacturing issues
  - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting





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## Multi-IC Technology Development Programs

(open to eligible Awardees from participating ICs)

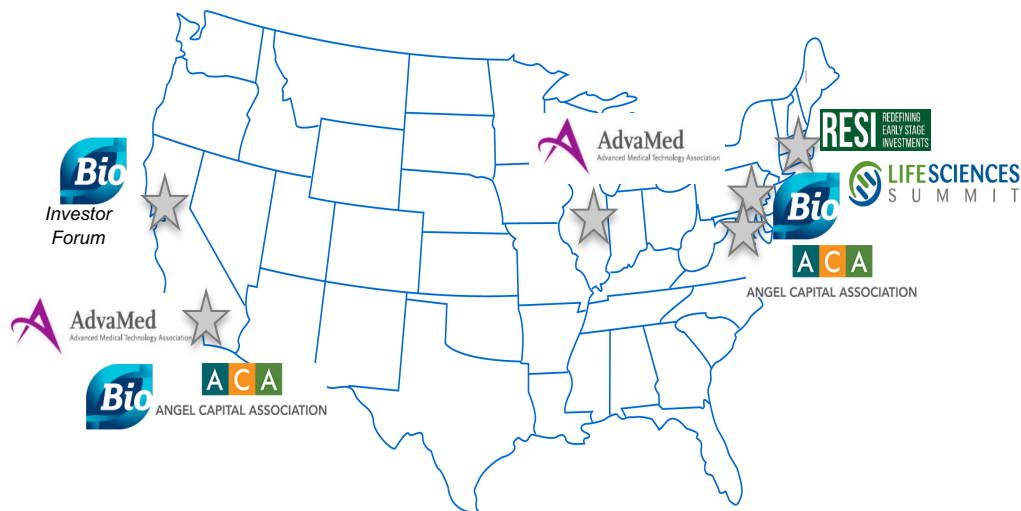
### I-Corps™ at NIH

An intensive *Entrepreneurial Immersion* course for scientists



12 Participating ICs + CDC

### Facilitating Partnerships





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# Research Training & Career Development

<https://researchtraining.nih.gov/>

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Clinical Residency

Early Research Career Development

Established Investigator Research Development and Mentoring

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## For More Information

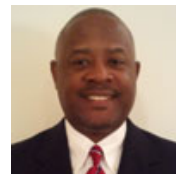


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### Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email [LISTSERV@LIST.NIH.GOV](mailto:LISTSERV@LIST.NIH.GOV) with the following text in the message body: **subscribe SBIR-STTR your name**
- [NIH Guide for Grants and Contracts](#) (weekly notification)
-  Follow us on Twitter: [@NIHsbir](https://twitter.com/NIHsbir)
- Read our [NIH SBIR/STTR Notable Successes](#)
- [Connect with Us](#)
- Email: [sbir@od.nih.gov](mailto:sbir@od.nih.gov)

